

PATIENT INFORMATION

CLARINEX-D® (CLA-RI-NEX) 12 Hour Extended Release Tablets (desloratadine and pseudoephedrine sulfate)

Read the Patient Information that comes with CLARINEX-D 12 Hour Extended Release Tablets before you start taking it and each time you get a refill. There may be new information. This leaflet is a summary of the information for patients. Your doctor or pharmacist can give you additional information. This leaflet does not take the place of talking to your doctor about your medical condition or treatment.

What is CLARINEX-D® 12 Hour Extended Release Tablets?

CLARINEX-D 12 Hour Extended Release Tablets is a prescription medicine that contains the medicines desloratadine (an antihistamine) and pseudoephedrine (a nasal decongestant). CLARINEX-D 12 Hour Extended Release Tablets is used to help control the symptoms of seasonal allergic rhinitis (sneezing, stuffy nose, runny nose and itching of the nose) in adults and children 12 years and older.

CLARINEX-D 12 Hour Extended Release Tablets is not for children under 12 years of age.

Who should not take CLARINEX-D® 12 Hour Extended Release Tablets?

Do not take CLARINEX-D 12 Hour Extended Release Tablets if you:

- are allergic to desloratadine or pseudoephedrine sulfate or any of the ingredients in CLARINEX-D 12 Hour Extended Release Tablets. See the end of this leaflet for a complete list of ingredients in CLARINEX-D 12 Hour Extended Release Tablets.
- are allergic to loratadine (Alavert, Claritin)
- have narrow-angle glaucoma
- have problems with urination (urinary retention)
- take a Monoamine Oxidase Inhibitor (MAOI) medicine to treat depression, or if you stopped taking an MAOI medicine within the last 2 weeks. Ask your doctor or pharmacist if you are not sure if you take an MAOI medicine.
- have severe high blood pressure
- have severe heart disease

Talk to your doctor before taking this medicine if you have any of these conditions.

What should I tell my doctor before taking CLARINEX-D® 12 Hour Extended Release Tablets?

Before you take CLARINEX-D 12 Hour Extended Release Tablets, tell your doctor if you:

- have any of the conditions listed in the section "Who should not take CLARINEX-D 12 Hour Extended Release Tablets?"
- diabetes
- hyperthyroidism
- have prostate problems
- have liver or kidney problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if CLARINEX-D 12 Hour Extended Release Tablets will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. CLARINEX-D 12 Hour Extended Release Tablets **can pass into your breast milk**. Talk to your doctor about the best way to feed your baby if you take CLARINEX-D 12 Hour Extended Release Tablets.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal supplements. CLARINEX-D® 12 Hour Extended Release Tablets may affect the way other medicines work, and other medicines may affect how CLARINEX-D 12 Hour Extended Release Tablets works. Especially tell your doctor if you take:

- Monoamine Oxidase Inhibitors (MAOIs). You should not use CLARINEX-D 12 Hour Extended Release Tablets if you take an MAOI or within 2 weeks of stopping an MAOI.
- methyldopa
- reserpine (Serpalan)
- digitalis (Digoxin, Lanoxicaps, Lanoxin) ketoconazole (Nizoral)
- erythromycin (Ery-tab, Eryc, PCE)
- azithromycin (Zithromax, Zmax)
- antihistamines
- other decongestant medicines

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

How should I take CLARINEX-D® 12 Hour Extended Release Tablets?

Take CLARINEX-D 12 Hour Extended Release Tablets exactly as your doctor tells you to take it.

- CLARINEX-D 12 Hour Extended Release Tablets can be taken with or without food.
- Swallow CLARINEX-D 12 Hour Extended Release Tablets whole. **Do not break, crush, or chew** CLARINEX-D 12 Hour Extended Release Tablets before swallowing. If you cannot swallow CLARINEX-D 12 Hour Extended Release Tablets whole, tell your doctor. You may need a different medicine.
- Take **1** CLARINEX-D 12 Hour Extended Release Tablet 2 times a day (every 12 hours).

What are the possible side effects of CLARINEX-D® 12 Hour Extended Release Tablets?

CLARINEX-D 12 Hour Extended Release Tablets may cause serious side effects, including:

- Cardiovascular and central nervous system effects, such as
 - unable to sleep (insomnia)
 - dizziness
 - weakness
 - tremor
 - irregular heart beat
 - seizure
 - low blood pressure
- Increased sleepiness or tiredness can happen if you take more CLARINEX-D 12 Hour Extended Release Tablets than your doctor prescribed to you.

- Allergic reactions. Stop taking CLARINEX-D 12 Hour Extended Release Tablets and call your doctor right away or get emergency help if you have any of these symptoms:
 - rash
 - itching
 - hives
 - swelling of your lips, tongue, face, and throat
 - shortness of breath or trouble breathing
- Severe skin reactions including signs and symptoms such as fever, reddening of the skin, or many small pimples

The most common side effects of CLARINEX-D 12 HOUR Extended Release Tablets include:

- unable to sleep (insomnia)
- sore throat
- headache
- dizziness
- dry mouth
- nausea
- tiredness
- loss of appetite
- sleepiness

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of CLARINEX-D 12 Hour Extended Release Tablets. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store CLARINEX-D® 12 Hour Extended Release Tablets?

- Store CLARINEX-D 12 Hour Extended Release Tablets at 59°F to 86°F (15°C to 30°C)
- Keep CLARINEX-D 12 Hour Extended Release Tablets dry and out of the light.

Keep CLARINEX-D 12 Hour Extended Release Tablets and all medicines out of the reach of children.

General information about CLARINEX-D® 12 Hour Extended Release Tablets

Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. Do not use CLARINEX-D 12 Hour Extended Release Tablets for a condition for which it was not prescribed. Do not give CLARINEX-D 12 Hour Extended Release Tablets to other people, even if they have the same condition you have. It may harm them.

This patient information leaflet summarizes the most important information about CLARINEX-D 12 Hour Extended Release Tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about CLARINEX-D 12 Hour Extended Release Tablets that is written for health professionals.

What are the ingredients in CLARINEX-D® 12 Hour Extended Release Tablets?

Active ingredients: desloratadine and pseudoephedrine sulfate

Inactive ingredients: hypromellose USP, microcrystalline cellulose NF, povidone USP, silicon dioxide NF, magnesium stearate NF, corn starch NF, edetate disodium USP, citric acid anhydrous USP, stearic acid NF, and FD&C Blue No. 2 aluminum lake dye.

Manufactured for: Organon LLC, a subsidiary of
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